UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF TEXAS
VICTORIA DIVISION

CALVIN TIMBERLAKE, *et al.*,	§	
	§	
Plaintiffs,	§	
	§	
v.	§	**CIVIL ACTION NO. V-08-4**
	§	
SYNTHES SPINE CO., L.P., *et al.*,	§	
	§	
Defendants.	§	

MEMORANDUM OPINION & ORDER

Ripe for ruling is Defendants' Viscogliosi Brothers L.L.C., Marc R. Viscogliosi, John J. Viscogliosi, and Anthony G. Viscogliosi ("Defendants") Rule 9(b) Motion to Dismiss. (Dkt. No. 45.)[1] After considering the motion, response, reply, and applicable law, the Court is of the opinion that Defendants' motion should be GRANTED.

I. Factual and Procedural Background

Plaintiffs brought this action after Calvin Timberlake and Anastasia Scott each underwent surgery implanting the artificial intervertebral disc, ProDisc. Both devices failed, requiring Mr. Timberlake and Ms. Scott to undergo a second surgery and causing them permanent injury. In their Complaint, Plaintiffs allege causes of action for fraud/misrepresentation, violation of the FDA approval process, negligence, strict liability, breach of warranty, and conspiracy. (Dkt. No. 69.) Relevant to this motion are Plaintiffs' claims for fraud and misrepresentation.

Plaintiffs contend that Defendants formed Spine Solutions, Inc. to obtain FDA approval for and eventually market the ProDisc. In furtherance of this endeavor, Defendants solicited physicians

1. Before the Court could rule on Defendants' motion, Plaintiffs Calvin Timberlake and Karen Timberlake filed their Second Amended Original Complaint, adding Anastasia Scott and Matthew Scott as plaintiffs in this case. (Dkt. No. 69.) While Defendants' motion complains of Plaintiffs' First Amended Original Complaint (Dkt. No. 8), the substance and language of Plaintiffs' fraud claims in both complaints are identical. Plaintiffs made no attempt to plead fraud with greater specificity than before or otherwise correct any deficiencies as alleged by Defendants. Thus, the Court will construe Defendants' motion as a motion to dismiss Plaintiffs' Second Amended Original Complaint.

to conduct the clinical investigations of the ProDisc who were also willing to invest in Spine Solutions. According to Plaintiffs, Defendants stated that having investor-physicians conduct the clinical trials would result in their ability to more readily obtain other investors and would ensure that the physicians were "in [their] pocket" so that the outcome of the clinical trials would be favorable. Defendants specifically solicited Dr. Jack Zigler of the Texas Back Institute in Plano, Texas to lead the clinical trials and were successful in locating approximately a dozen other doctors who agreed to invest in their company while also participating in the clinical trials. On April 4, 2003, Synthes Spine, Inc. ("Synthes") purchased Spine Solutions. Synthes completed the clinical trials and ultimately applied for and received pre-market approval from the FDA for use of the ProDisc.

Prior to the ProDisc's approval by the FDA and while it was still undergoing clinical trials, Mr. Timberlake began researching alternative treatment options for his degenerative disc disease because traditional treatments were not resolving his condition. Around the same time, Ms. Scott also began researching artificial disc replacement after being told by her physician that she would require an implantation to treat her degenerative disc disease. According to their Complaint, both Mr. Timberlake and Ms. Scott read multiple reports of the successes of the ProDisc trials and discussed the possibility of having the ProDisc implanted with their doctors, and both relied on the reports in their ultimate decision to have the ProDisc implanted.

Plaintiffs allege the Defendants committed fraud by: (1) failing to disclose that doctors and clinics that were participating in the clinical trials would benefit financially if the FDA approved the device and from the sale of the ProDisc; (2) failing to disclose the financial interest of the Texas Back Institute and Dr. Zigler if the ProDisc was approved for sale; and (3) providing incomplete and misleading information concerning the clinical trials. Defendants have filed the instant motion under Federal Rule of Civil Procedure 9(b), arguing that Plaintiffs' claims for fraud and misrepresentation

should be dismissed because Plaintiffs have not alleged fraud with particularity as required by Federal Rule of Civil Procedure 9(b).

II. Standard of Review

Despite arising under Texas common law, Plaintiffs' fraud claims are still subject to the heightened pleading requirements of the Federal Rules of Civil Procedure. *Dorsey v. Portfolio Equities, Inc.*, 540 F.3d 333, 338—39 (5th Cir. 2008) (citing *Abrams v. Baker Hughes Inc.*, 292 F.3d 424, 430 (5th Cir. 2002)). Rule 9(b) provides: "In alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake." FED. R. CIV. P. 9(b). A dismissal for failure to plead fraud with particularity as required by Rule 9(b) is treated as a Rule 12(b)(6) dismissal for failure to state a claim. *Lovelace v. Software Spectrum, Inc.*, 78 F.3d 1015, 1017 (5th Cir. 1996). "[A] plaintiff's failure to meet the specific pleading requirements should not automatically or inflexibility [sic] result in dismissal of the complaint with prejudice to re-filing." *Hart v. Bayer Corp.*, 199 F.3d 239, 248 n.6 (5th Cir. 2000) (citing *Cates v. International Telephone and Telegraph Corp.*, 756 F.2d 1161, 1180 (5th Cir. 1985)). "Although a court may dismiss the claim, it should not do so without granting leave to amend, unless the defect is simply incurable or the plaintiff has failed to plead with particularity after being afforded repeated opportunities to do so." *Id.* (citing *O'Brien v. National Property Analysts Partners*, 936 F.2d 674, 675—76 (2d Cir. 1991)).

III. Discussion

Defendants contend Plaintiffs' claims for fraud and misrepresentation should be dismissed for failure to satisfy the requirements of Rule 9(b) because Plaintiffs "fail to plead allegations of fraud and misrepresentation with particularity" and "fail to specify which Defendants allegedly committed each fraudulent act." (Dkt. No. 45 at 3.)

A. Failure to plead with particularity

"What constitutes 'particularity' will necessarily differ with the facts of each case . . . ." *Guidry v. Bank of LaPlace*, 954 F.2d 278, 288 (5th Cir. 1992). Here, Plaintiffs' allegations of fraud fall into two categories: (1) fraud by nondisclosure and (2) fraud by affirmative misrepresentation. The Court will consider each in turn.

1. Fraud by Nondisclosure

"Fraudulent concealment or non-disclosure is a sub-category of fraud that occurs when a party with a duty to disclose a material fact fails to disclose that fact." *GMAC Commercial Mortg. Corp. v. East Texas Holdings, Inc.*, 441 F. Supp. 2d 801, 807 (E.D. Tex. 2006) (citing *Schlumberger Technology Corp. v. Swanson*, 959 S.W.2d 171, 181 (Tex. 1997)). To state a claim for common-law fraud based on nondisclosure, Texas law requires a plaintiff to allege: (1) the defendant concealed or failed to disclose a material fact that the defendant knew the plaintiff was ignorant of or did not have the opportunity to discover; (2) the defendant intended to induce the plaintiff to take some action by concealing or failing to disclose the material fact; and (3) the plaintiff suffered as a result of acting on the defendant's nondisclosure. *Dorsey*, 540 F.3d at 341 (citing *Bradford v. Vento*, 48 S.W.3d 749, 754—55 (Tex. 2001)).

A plaintiff must also allege facts showing the defendant had a duty to disclose the material fact. *Union Pacific Resources Group, Inc. v. Rhone-Poulenc, Inc.*, 247 F.3d 574, 586 (5th Cir. 2001). An affirmative duty to disclose may arise by operation of law (1) where there is a fiduciary or confidential relationship between the parties; (2) where a person voluntarily discloses some information; (3) when a person makes a representation and new information makes that earlier misrepresentation false or misleading; and (4) when a person makes a partial disclosure and conveys a false impression. *In re Enron Corporation Securities, Derivative & "ERISA" Litigation*, 540 F.

Supp. 2d 759, 771 (S.D. Tex. 2007) (citing *Hoggett v. Brown*, 971 S.W.2d 472, 487 (Tex. App.—Houston [14th Dist.] 1997, pet. denied). *See also Union Pacific Resources*, 247 F.3d at 586; *GMAC Commercial*, 441 F. Supp. 2d at 808.

Rule 9(b) imposes an additional obligation on plaintiffs claiming fraud by nondisclosure to "'plead the type of facts omitted, the place in which the omissions should have appeared, and the way in which the omitted facts made the representations misleading.'" *Carroll v. Fort James Corp.*, 470 F.3d 1171, 1174 (5th Cir. 2006) (quoting *United States ex. rel. Riley v. St. Luke's Hosp.*, 355 F.3d 370, 381 (5th Cir. 2004)).

In their Second Amended Complaint, Plaintiffs allege Defendants committed fraud by nondisclosure by:

> Intentionally . . . failing to disclose to the FDA, to the public, to surgeons who were not investors in the companies, and to Calvin Timberlake and Anastasia Scott that doctors and clinics that were participating in the clinical trials would benefit financially if the FDA approved the device and from the sale of the devices; and
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> Intentionally . . . failing to disclose to the FDA, to the public, to surgeons who were not investors in the companies, and to Calvin Timberlake and Anastasia Scott that Dr. Jack Zigler, the lead investigator for the ProDisc FDA trials and the lead author on published results and his clinic, The Texas Back Institute and other doctors at The Texas Back Institute would benefit financially if the FDA approved the device and from the sale of the devices; and
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> Intentionally providing to the FDA, to the public, to physicians, and to Calvin Timberlake and Anastasia Scott, incomplete . . . information concerning its clinical trials; and
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> . . .
>
> Intentionally failing to disclose to the FDA, to the public, to physicians, and to Calvin Timberlake and Anastasia Scott problems with ProDisc's design and performance.

(Dkt. No. 69 ¶¶ 60(a),(b),(d) & (f)).

Plaintiffs have adequately plead the "type of facts omitted" with respect to the financial interest of the doctors and clinics that were participating in the clinical trials, including the Texas Back Institute and Dr. Zigler. However, Plaintiffs fail to describe the "problems with ProDisc's

design and performance" Defendants allegedly failed to disclose as well as what made the information Defendants provided to the FDA, to the public, to physicians, and to Calvin Timberlake and Anastasia Scott "incomplete."[2] Plaintiffs also fail to allege facts establishing that Defendants had a duty to disclose any of the allegedly omitted facts to the FDA, to the public, to surgeons who were not investors in the companies, or to Calvin Timberlake and Anastasia Scott.

In sum, Plaintiffs "clearly fail to indicate 'the place in which the omissions should have appeared'" and "allege no facts showing when, if ever, it was incumbent upon [Defendants] . . . to disclose any information to them at all, nor how [Defendants] should have done so." *Carroll*, 470 F.3d at 1174 (quoting *Riley*, 355 F.3d at 381). Therefore, the Court is of the opinion that Plaintiffs have failed to plead fraud by nondisclosure with particularity as required by Rule 9(b).

2. Fraud by Affirmative Misrepresentation

Under Texas law, in order to state a claim for common-law fraud based upon an affirmative misrepresentation, a plaintiff must allege that the defendant made "a material misrepresentation, which was false, and which was either known to be false when made or was asserted without knowledge of the truth, which was intended to be acted upon, which was relied upon, and which caused injury." *Dorsey*, 540 F.3d at 341 (quoting *Johnson & Johnson Med., Inc. v. Sanchez*, 924 S.W.2d 925, 929—30 (Tex. 1996)). Under Rule 9(b), a plaintiff must also "specify the statements contended to be fraudulent, identify the speaker, state when and where the statements were made, and explain why the statements were fraudulent." *Herrmann Holdings Ltd. v. Lucent Techs. Inc.*, 302 F.3d 552, 564—65 (5th Cir. 2002) (internal quotations and citations omitted). Simply put, Rule 9(b) requires a plaintiff to set forth "the who, what, when, where, and how" of the events at issue.

2. In an earlier section of their Complaint, Plaintiffs refer to other facts of which Mr. Timberlake and Ms. Scott were unaware at the time they underwent surgery, including that "the doctors had intentionally left out of the reported results of the studies a large number of patients who had received implantation of the ProDisc, many of whom, upon information and belief, had outcomes less favorable than those that were included in the reports of the studies" and that "there was no acceptable salvage surgery in the event that the artificial disc failed and that removing a failed artificial disc would be a life-threatening surgery." (*Id.* ¶¶ 16 & 35.) It is unclear whether Plaintiffs intend to allege that these are the omitted facts that rendered the information Defendants provided regarding the clinical trials incomplete.

ABC Arbitrage Plaintiffs Group v. Tchuruk, 291 F.3d 336, 350 (5th Cir. 2002) (internal quotations and citations omitted).

Defendants allege that Plaintiffs' Complaint does not sufficiently state: (1) the content of any allegedly false statements; (2) when the statements were made; (3) where the statements were made; (4) why the statements are false; or (5) how Plaintiffs specifically relied on each statement. (Dkt. No. 45 at 4.) Plaintiffs, however, maintain that the "what, when, where, and how" of the alleged statements are "catalogued with extraordinary precision." (Dkt. No. 49 at 3.)

a. What misrepresentations were made?

Plaintiffs contend they adequately answered the question of "what" misrepresentations were made by directing the Court to the section of their Complaint in which they allege Defendants made the following intentional, material misrepresentations:

> [Representations regarding] the nature, history and result of clinical trials; and
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> . . .
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> [R]epresentations . . . regarding the performance capabilities of the ProDisc; and
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> . . .
>
> [R]epresentations . . . which exceeded the performance capabilities presented by the defendants to the FDA; and
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> [R]epresentations . . . which were never considered by the FDA.

(Dkt. No. 69 ¶¶ 60(c), (e), (g) & (h)).[3] Plaintiffs also allege Defendants intentionally provided "misleading information concerning its clinical trials." (*Id.* ¶ 60(d).)

The Court rejects Plaintiffs' assertion that "[g]reater specificity cannot be reasonably expected." (Dkt. No. 49 at 4.) With respect to Plaintiffs' claim that Defendants made intentional

3. It is unclear whether Plaintiffs also allege that Defendants affirmatively misrepresented that Dr. Zigler, The Texas Back Institute, and the other doctors and clinics that were participating in the clinical trials would *not* benefit financially if the FDA approved the ProDisc. To the extent Plaintiffs intend to make this allegation, Plaintiffs have cited no statement in which Defendants deny that the doctors participating in the trials were also investors, nor have Plaintiffs cited any statement by Defendants listing certain ProDisc investors, while omitting Dr. Zigler, The Texas Back Institute, and other allegedly interested doctors and clinics. *See Hernandez v. Ciba-Geigy Corp. USA*, 200 F.R.D. 285, 292 (S.D. Tex. 2001).

misrepresentations regarding the "nature, history and result of clinical trials," Plaintiffs fail to cite any specific statement by Defendants and fail explain with any degree of detail *how* Defendants misrepresented each aspect of the clinical trials. Plaintiffs' allegations that Defendants intentionally provided "misleading information concerning its clinical trials" and misrepresented the "performance capabilities" and "safety and effectiveness" of the ProDisc are insufficient for the same reason. Finally, Plaintiffs fail to identify what representations Defendants made to doctors, patients, and the general public "which were never considered by the FDA."

Plaintiffs' response also directs the Court's attention to "[t]he paragraph of the Complaint immediately preceding that quoted above," which "expressly incorporates by reference all earlier allegations." (*Id.* at 4.) However, Plaintiffs' argument stops there, and as Defendants point out, Defendants should not be required to "sort through the prior [58] paragraphs of the complaint in an attempt to clear Plaintiffs' murky waters." (Dkt. No. 55 at 2.) Nonetheless, the Court did sort through Plaintiffs' Complaint and has identified three statements related to the clinical trials, which Mr. Timberlake and Ms. Scott claim they read and relied on in their decision to have the ProDisc implanted. Plaintiffs allegedly read claims that the ProDisc (1) "had been through rigorous testing conducted by numerous doctors with fantastic results;" (2) "had been found to result in significantly better outcomes than the alternative treatments;" and (3) "would provide [them] a faster recovery and allow [them] to return to work faster." (*Id.* ¶¶ 14, 15, 33 & 34.) However, as described below, Plaintiffs fail to describe with specificity when and where Defendants allegedly made each representation as well as how each statement was false.

b. Where was each misrepresentation made?

Plaintiffs contend they explicitly answered the question of "where" the misrepresentations were made—"in reports of the ProDisc clinical trials." (Dkt. No. 49 at 5.) However, Plaintiffs' Complaint refers not only to the "multiple reports of the successes of the ProDisc artificial disc

trials" allegedly read by both Mr. Timberlake and the Scotts, but also to "claims by Dr. Zigler" and "claims made by the defendants, and substantiated by the doctors performing the studies." (*Id.* ¶¶ 14, 15, 33 & 34.) In addition, the Scotts "read astonishing claims of successful results by the Defendants and Dr. Bertagnoli regarding the ProDisc" and studied "the results of the F.D.A. [sic] clinical trials presided over by Dr. Jack Zigler at the Texas Back Institute in Plano, Texas." (*Id.* ¶ 28.)

While Plaintiffs refer to "multiple reports" and "claims" made by a number of individuals, Plaintiffs fail to distinguish among the various reports, identify the reports with specificity, or provide even a cursory citation so that the Court—and more importantly the Defendants—can locate these documents. Plaintiffs also fail to pinpoint in which of the numerous reports they read each alleged misrepresentation.[4]

c. When was each misrepresentation made?

Plaintiffs contend they explicitly answered the question of "when" the misrepresentations were made—"repeatedly between May 2001 and December 2006." (Dkt. No. 49 at 5.) However, Plaintiffs' reference to a period of time spanning more than five years is too broad to provide Defendants with adequate notice of when each alleged misrepresentation was made. *See Shushany v. Allwaste, Inc.*, 992 F.2d 517, 522 n.7 (5th Cir. 1993) (citing *Decker v. Massey-Ferguson*, 681 F.2d 111, 117 (2d Cir. 1982) (allegation that fraudulent acts took place in the "fall of 1977" insufficient as to time and place of fraud)). If Defendants' alleged misrepresentations were repeated in the "multiple reports" of the ProDisc clinical trials, Plaintiffs should identify, or at least approximate, the publication date of each report.

4. In fact, Plaintiffs' only citation to a specific factual statement, in a specific text, attributable to a specific author, was in reference to Dr. Bertagnoli's "claims of 98.2% success (Bertagnoli & Kumer, Eur Spine J, 2002;11 Suppl 2:131-6.)." (*Id.* ¶ 28.) However, Plaintiffs do not allege this statement is false, nor is Dr. Bertagnoli even a Defendant in this case.

d. How was each misrepresentation false?

Plaintiffs contend they explicitly answered the question of "how" the alleged representations were false—"because they exaggerated the performance capabilities of the ProDisc." (Dkt. No. 49 at 5.) Plaintiffs direct the Court to the portion of their Complaint that alleges:

> Defendants made misrepresentations . . . regarding the clinical trials, the performance capabilities of the ProDisc, the safety of the ProDisc, [and] problems with the disc's design and performance; and
>
> Defendants made intentional express representations . . . that exceeded the performance capabilities presented by the defendants to the FDA. These representations were false . . . .

(Dkt. No. 64 ¶¶ 55 & 56.)

Plaintiffs' attempt at describing "how" each representation was false is insufficient for two reasons. First, Plaintiffs fail to cite a single statement made by Defendants to the FDA regarding the performance capabilities of the ProDisc, so that Defendants may determine whether any exaggerations were made. Second, there are numerous ways in which each alleged misrepresentation could be false.[5]

e. How did Plaintiffs rely on each misrepresentation?

Despite Defendants' assertion to the contrary, Rule 9(b) does not require that Plaintiffs plead reliance with particularity or state how they specifically relied on each statement. Plaintiffs' allegation that Mr. Timberlake and Ms. Scott relied on Defendants' misrepresentations in their decision to have the ProDisc implanted (*Id.* ¶ 63) is sufficient.

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5. With respect to Plaintiffs' allegation that Defendants claimed "the ProDisc had been through rigorous testing conducted by numerous doctors with fantastic results," maybe the testing was not rigorous; maybe the testing was not conducted by numerous doctors; maybe the results were not "fantastic;" or maybe the ProDisc hadn't been through testing at all. Likewise, with respect to the statement that "the ProDisc had been found to result in significantly better outcomes than the alternative treatments," maybe the outcomes were better, but were not statistically significant; maybe the outcomes were the same; maybe the outcomes were worse; or maybe researchers failed to even compare the outcomes of the ProDisc trials with those of other alternative treatments. Plaintiffs also fail to define the term "outcome" and fail to explain with which alternative treatments the ProDisc was being compared, which leads to further room for interpretation. Finally, the representation that "the ProDisc would provide [Mr. Timberlake and Ms. Scott] a faster recovery and allow [them] to return to work faster" could be interpreted in a number of ways, mainly because Plaintiffs fail to answer the basic question: "Faster than what?"

Because Plaintiffs fail to describe with specificity when and where Defendants allegedly made each representation as well as how each representation was false, the Court is of the opinion that Plaintiffs have failed to plead fraud by affirmative representation with the particularity required by Rule 9(b).

B. Failure to Distinguish Among Defendants

Defendants further assert that Plaintiffs' claims for fraud and misrepresentation should be dismissed because Plaintiffs ignore the strict requirements of Rule 9(b) "by making broad brush allegations as to all Defendants" and "fail[ing] to give Defendants adequate notice of the role each of them purportedly played in the alleged fraud." (Dkt. No. 45 at 4.)

The Fifth Circuit has explicitly rejected the "group pleading" doctrine, and instead requires plaintiffs to delineate among defendants in their responsibility for allegedly fraudulent activities. *Southland Securities Corp. v. INSpire Ins. Solutions, Inc*., 365 F.3d 353, 365 (5th Cir. 2004). Courts should "not construe allegations contained in the Complaint against the 'defendants' as a group as properly imputable to any particular individual defendant unless the connection between the individual defendant and the allegedly fraudulent statement is specifically pleaded." *Id. See also In re Alamosa Holdings, Inc.*, 382 F. Supp. 2d 832, 857 (N.D. Tex. 2005) ("Any allegations in the Complaint made against 'Defendants' (plural or group) do not meet the requirements of pleading allegations of fraud."); *Hernandez v. Ciba-Geigy Corp. USA*, 200 F.R.D. 285, 291 (S.D. Tex. 2001) (citing *Zuckerman v. Foxmeyer Health Corp.*, 4 F. Supp. 2d 618, 622 (N.D. Tex. 1998) ("[T]he plaintiff is obligated to distinguish among those they sue and enlighten each defendant as to his or her part in the alleged fraud.")).

Plaintiffs name Synthes Spine Company L.P., Spine Solutions Inc., Synthes (U.S.A.), SMGT Inc., Viscogliosi Brothers L.L.C., Marc R. Viscogliosi, John J. Viscogliosi, and Anthony G. Viscogliosi as defendants in this case, but fail to distinguish among these individuals and entities

with respect to their fraud claims. Instead, Plaintiffs allege "Defendants [as a group] made . . . intentional, material misrepresentations and committed fraud," without identifying which defendant or defendants were responsible for each misrepresentation. (Dkt. No. 64 ¶ 60.) Plaintiffs also attribute a number of the alleged misrepresentations to individuals who are not named as defendants in this case. For example, Plaintiffs refer to "claims made by Dr. Zigler and others," "astonishing claims of successful results by . . . Dr. Bertagnoli," and "representations made by . . . the doctors who performed the studies." (*Id.* ¶¶ 15, 17, 28 & 34.) In order to impute these statements to Defendants, Plaintiffs must specifically plead the connection between each individual defendant and each allegedly fraudulent statement. *See Southland Securities*, 365 F.3d at 365.

IV. Conclusion

Plaintiffs have failed to meet the specific pleading requirements of Rule 9(b). Defendants' Rule 9(b) Motion to Dismiss (Dkt. No. 45) is hereby GRANTED, and Plaintiffs' claims for fraud and misrepresentation are DISMISSED without prejudice. However, the Court is of the opinion that Plaintiffs could state a claim upon which relief could be granted if given the opportunity to amend their pleadings. Therefore, Plaintiffs are granted leave to amend their pleadings in a manner consistent with this Order no later than thirty (30) days after the entry of this Order, or their fraud claims will be dismissed with prejudice.

It is so ORDERED.

SIGNED this 31st day of March, 2009.

JOHN D. RAINEY
UNITED STATES DISTRICT JUDGE